

<div>Department of Health and Human Services Public Health Services</div> <div>Grant Application</div> <div>Do not exceed character length restrictions indicated.</div>		LEAVE BLANK—FOR PHS USE ONLY.			
		Type	Activity	Number	
		Review Group		Formerly	
		Council/Board (Month, Year)		Date Received	
1. TITLE OF PROJECT (Do not exceed 81 characters, including spaces and punctuation.)					
2. RESPONSE TO SPECIFIC REQUEST FOR APPLICATIONS OR PROGRAM ANNOUNCEMENT OR SOLICITATION NO YES (If “Yes,” state number and title) Number: Title:					
3. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR			New Investigator	No	Yes
3a. NAME (Last, first, middle)			3b. DEGREE(S)		3h. eRA Commons User Name
3c. POSITION TITLE			3d. MAILING ADDRESS (Street, city, state, zip code)		
3e. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT					
3f. MAJOR SUBDIVISION					
3g. TELEPHONE AND FAX (Area code, number and extension) TEL: FAX:					
4. HUMAN SUBJECTS RESEARCH No Yes		4b. Human Subjects Assurance No.		5. VERTEBRATE ANIMALS No Yes	
4a. Research Exempt No Yes		4c. Clinical Trial No Yes		4d. NIH-defined Phase III Clinical Trial No Yes	
		If “Yes,” Exemption No.		5a. If “Yes,” IACUC approval Date	
				5b. Animal welfare assurance no.	
6. DATES OF PROPOSED PERIOD OF SUPPORT (month, day, year—MM/DD/YY) From Through		7. COSTS REQUESTED FOR INITIAL BUDGET PERIOD 7a. Direct Costs (\$)		8. COSTS REQUESTED FOR PROPOSED PERIOD OF SUPPORT 7b. Total Costs (\$)	
				8a. Direct Costs (\$)	
				8b. Total Costs (\$)	
9. APPLICANT ORGANIZATION Name Address			10. TYPE OF ORGANIZATION Public: → Federal State Local Private: → Private Nonprofit For-profit: → General Small Business Woman-owned Socially and Economically Disadvantaged		
			11. ENTITY IDENTIFICATION NUMBER DUNS NO. Cong. District		
12. ADMINISTRATIVE OFFICIAL TO BE NOTIFIED IF AWARD IS MADE Name Title Address Tel: FAX: E-Mail:			13. OFFICIAL SIGNING FOR APPLICANT ORGANIZATION Name Title Address Tel: FAX: E-Mail:		
14. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ASSURANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.			SIGNATURE OF PI/PD NAMED IN 3a. (In ink. “Per” signature not acceptable.)		DATE
15. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.			SIGNATURE OF OFFICIAL NAMED IN 13. (In ink. “Per” signature not acceptable.)		DATE

Principal Investigator/Program Director (Last, First, Middle):

DESCRIPTION: See instructions. State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project (i.e., relevance to the **mission of the agency**). Describe concisely the research design and methods for achieving these goals. Describe the rationale and techniques you will use to pursue these goals.

In addition, in two or three sentences, describe in plain, lay language the relevance of this research to **public** health. If the application is funded, this description, as is, will become public information. Therefore, do not include proprietary/confidential information. **DO NOT EXCEED THE SPACE PROVIDED.**

PERFORMANCE SITE(S) (organization, city, state)

Principal Investigator/Program Director (Last, First, Middle):

KEY PERSONNEL. See instructions. *Use continuation pages as needed* to provide the required information in the format shown below. Start with Principal Investigator. List all other key personnel in alphabetical order, last name first.

Name	eRA Commons User Name	Organization	Role on Project
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OTHER SIGNIFICANT CONTRIBUTORS

Name	Organization	Role on Project
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Human Embryonic Stem Cells No Yes

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: <http://stemcells.nih.gov/registry/index.asp>. *Use continuation pages as needed.*

If a specific line cannot be referenced at this time, include a statement that one from the Registry will be used.

Cell Line

Disclosure Permission Statement. Applicable to SBIR/STTR Only. See SBIR/STTR instructions.

Yes

No

The name of the principal investigator/program director must be provided at the top of each printed page and each continuation page.

RESEARCH GRANT TABLE OF CONTENTS

Page Numbers

Face Page	1
Description, Performance Sites, Key Personnel, Other Significant Contributors, and Human Embryonic Stem Cells	_____
Table of Contents	_____
Detailed Budget for Initial Budget Period (or Modular Budget)	_____
Budget for Entire Proposed Period of Support (not applicable with Modular Budget)	_____
Budgets Pertaining to Consortium/Contractual Arrangements (not applicable with Modular Budget)	_____
Biographical Sketch – Principal Investigator/Program Director <i>(Not to exceed four pages)</i>	_____
Other Biographical Sketches <i>(Not to exceed four pages for each – See instructions)</i>	_____
Resources	_____
 Research Plan	 _____
Introduction to Revised Application <i>(Not to exceed 3 pages; SBIR/STTR Phase I not to exceed 1 page.)</i>	_____
Introduction to Supplemental Application <i>(Not to exceed one page)</i>	_____
A. Specific Aims	_____
B. Background and Significance	_____
C. Preliminary Studies/Progress Report/ Phase I Progress Report (SBIR/STTR Phase II ONLY)	_____
D. Research Design and Methods.....	_____
E. Human Subjects Research	_____
Protection of Human Subjects (Required if Item 4 on the Face Page is marked “Yes”).....	_____
Data and Safety Monitoring Plan (Required if Item 4 on the Face Page is marked “Yes” and a Phase I, II, or III clinical trial is proposed)	_____
Inclusion of Women and Minorities (Required if Item 4 on the Face Page is marked “Yes” and is Clinical Research)	_____
Targeted/Planned Enrollment Table (for new and continuing clinical research studies)	_____
Inclusion of Children (Required if Item 4 on the Face Page is marked “Yes”)	_____
F. Vertebrate Animals	_____
G. Literature Cited	_____
H. Consortium/Contractual Arrangements.....	_____
I. Resource Sharing	_____
J. Letters of Support (e.g., Consultants)	_____
Commercialization Plan (SBIR/STTR Phase II and Fast-Track ONLY)	_____
 Checklist	 _____

Appendix *(Five collated sets. No page numbering necessary for Appendix.)*Check if
Appendix is
Included

Appendices NOT PERMITTED for Phase I SBIR/STTR unless specifically solicited.....

Number of publications and manuscripts accepted for publication *(not to exceed 10)* _____

Other items (list): _____

Principal Investigator/Program Director (Last, First, Middle):

DETAILED BUDGET FOR INITIAL BUDGET PERIOD DIRECT COSTS ONLY					FROM	THROUGH	
PERSONNEL <i>(Applicant organization only)</i>		TYPE APPT. <i>(months)</i>	% EFFORT ON PROJ.	INST. BASE SALARY	DOLLAR AMOUNT REQUESTED <i>(omit cents)</i>		
NAME	ROLE ON PROJECT				SALARY REQUESTED	FRINGE BENEFITS	TOTAL
	Principal Investigator						
SUBTOTALS →							
CONSULTANT COSTS							
EQUIPMENT <i>(Itemize)</i>							
SUPPLIES <i>(Itemize by category)</i>							
TRAVEL							
PATIENT CARE COSTS		INPATIENT					
		OUTPATIENT					
ALTERATIONS AND RENOVATIONS <i>(Itemize by category)</i>							
OTHER EXPENSES <i>(Itemize by category)</i>							
CONSORTIUM/CONTRACTUAL COSTS				DIRECT COSTS			
SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD <i>(Item 7a, Face Page)</i>						\$	
CONSORTIUM/CONTRACTUAL COSTS				FACILITIES AND ADMINISTRATIVE COSTS			
TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD						\$	
SBIR/STTR Only: FEE REQUESTED							

BUDGET FOR ENTIRE PROPOSED PROJECT PERIOD DIRECT COSTS ONLY

BUDGET CATEGORY TOTALS		INITIAL BUDGET PERIOD <i>(from Form Page 4)</i>	ADDITIONAL YEARS OF SUPPORT REQUESTED			
			2nd	3rd	4th	5th
PERSONNEL: <i>Salary and fringe benefits. Applicant organization only.</i>						
CONSULTANT COSTS						
EQUIPMENT						
SUPPLIES						
TRAVEL						
PATIENT CARE COSTS	INPATIENT					
	OUTPATIENT					
ALTERATIONS AND RENOVATIONS						
OTHER EXPENSES						
CONSORTIUM/ CONTRACTUAL COSTS	DIRECT					
SUBTOTAL DIRECT COSTS <i>(Sum = Item 8a, Face Page)</i>						
CONSORTIUM/ CONTRACTUAL COSTS	F&A					
TOTAL DIRECT COSTS						
TOTAL DIRECT COSTS FOR ENTIRE PROPOSED PROJECT PERIOD						\$
SBIR/STTR Only Fee Requested						
SBIR/STTR Only: Total Fee Requested for Entire Proposed Project Period <small>(Add Total Fee amount to "Total direct costs for entire proposed project period" above and Total F&A/indirect costs from Checklist Form Page, and enter these as "Costs Requested for Proposed Period of Support on Face Page, Item 8b.)</small>						\$

JUSTIFICATION. Follow the budget justification instructions exactly. Use continuation pages as needed.

Principal Investigator/Program Director (Last, first, middle):

RESOURCES

FACILITIES: Specify the facilities to be used for the conduct of the proposed research. Indicate the performance sites and describe capacities, pertinent capabilities, relative proximity, and extent of availability to the project. Under "Other," identify support services such as machine shop, electronics shop, and specify the extent to which they will be available to the project. Use continuation pages if necessary.

Laboratory:

Clinical:

Animal:

Computer:

Office:

Other:

MAJOR EQUIPMENT: List the most important equipment items already available for this project, noting the location and pertinent capabilities of each.

CHECKLIST**TYPE OF APPLICATION** (Check all that apply.)

NEW application. (This application is being submitted to the PHS for the first time.)

REVISION of application number: _____

(This application replaces a prior unfunded version of a new, competing continuation, or supplemental application.)

COMPETING CONTINUATION of grant number: _____

(This application is to extend a funded grant beyond its current project period.)

INVENTIONS AND PATENTS

(Competing continuation appl. and Phase II only)

No

Previously reported

SUPPLEMENT to grant number: _____

(This application is for additional funds to supplement a currently funded grant.)

Yes. If "Yes,"

Not previously reported

CHANGE of principal investigator/program director.

Name of former principal investigator/program director: _____

CHANGE of Grantee Institution. Name of former institution: _____

FOREIGN application

Domestic Grant with foreign involvement

List Country(ies)

Involved: _____

SBIR Phase I

SBIR Phase II: SBIR Phase I Grant No. _____

SBIR Fast Track

STTR Phase I

STTR Phase II: STTR Phase I Grant No. _____

STTR Fast Track

1. PROGRAM INCOME (See instructions.)

All applications must indicate whether program income is anticipated during the period(s) for which grant support is request. If program income is anticipated, use the format below to reflect the amount and source(s).

Budget Period	Anticipated Amount	Source(s)

2. ASSURANCES/CERTIFICATIONS (See instructions.)

In signing the application Face Page, the authorized organizational representative agrees to comply with the following policies, assurances and/or certifications when applicable. Descriptions of individual assurances/certifications are provided in Part III. If unable to certify compliance, where applicable, provide an explanation and place it after this page.

•Human Subjects Research •Research Using Human Embryonic Stem Cells •Research on Transplantation of Human Fetal Tissue •Women and Minority Inclusion Policy •Inclusion of Children Policy •Vertebrate Animals •STTR ONLY: Certification of Research Institution Participation.

•Debarment and Suspension •Drug-Free Workplace (applicable to new [Type 1] or revised [Type 1] applications only) •Lobbying •Non-Delinquency on Federal Debt •Research Misconduct •Civil Rights (Form HHS 441 or HHS 690) •Handicapped Individuals (Form HHS 641 or HHS 690) •Sex Discrimination (Form HHS 639-A or HHS 690) •Age Discrimination (Form HHS 680 or HHS 690) •Recombinant DNA Research, Including Human Gene Transfer Research •Financial Conflict of Interest (except Phase I SBIR/STTR) •Smoke Free Workplace •Prohibited Research •Select Agents and Toxins

3. FACILITIES AND ADMINISTRATIVE COSTS (F&A)/ INDIRECT COSTS. See specific instructions.

DHHS Agreement dated: _____

No Facilities And Administrative Costs Requested.

DHHS Agreement being negotiated with _____

Regional Office.

No DHHS Agreement, but rate established with _____

Date _____

CALCULATION* (The entire grant application, including the Checklist, will be reproduced and provided to peer reviewers as confidential information.)

a. Initial budget period:	Amount of base \$ _____	x Rate applied _____	= F&A costs \$ _____
b. 02 year	Amount of base \$ _____	x Rate applied _____	= F&A costs \$ _____
c. 03 year	Amount of base \$ _____	x Rate applied _____	= F&A costs \$ _____
d. 04 year	Amount of base \$ _____	x Rate applied _____	= F&A costs \$ _____
e. 05 year	Amount of base \$ _____	x Rate applied _____	= F&A costs \$ _____
TOTAL F&A Costs \$			<div style="border: 2px solid black; width: 100px; height: 20px;"></div>

*Check appropriate box(es):

Salary and wages base

Modified total direct cost base

Other base (Explain)

Off-site, other special rate, or more than one rate involved (Explain)

Explanation (Attach separate sheet, if necessary.):

Principal Investigator/Program Director (Last, First, Middle):

Place this form at the end of the signed original copy of the application.
Do not duplicate.

PERSONAL DATA ON PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR

The Public Health Service has a continuing commitment to monitor the operation of its review and award processes to detect—and deal appropriately with—any instances of real or apparent inequities with respect to age, sex, race, or ethnicity of the proposed principal investigator/program director.

To provide the PHS with the information it needs for this important task, complete the form below and attach it to the signed original of the application after the Checklist. **Do not attach copies of this form to the duplicated copies of the application.**

Upon receipt of the application by the PHS, this form will be separated from the application. This form will **not** be duplicated, and it will **not** be a part of the review process. Data will be confidential, and will be maintained in Privacy Act record system 09-25-0036, "Grants: IMPAC (Grant/Contract Information)." The PHS requests the last four digits of the Social Security Number for accurate identification, referral, and review of applications and for management of PHS grant programs. Although the provision of this portion of the Social Security Number is voluntary, providing this information may improve both the accuracy and speed of processing the application. Please be aware that no individual will be denied any right, benefit, or privilege provided by law because of refusal to disclose this section of the Social Security Number. The PHS requests the last four digits of the Social Security Number under Sections 301(a) and 487 of the PHS Acts as amended (42 U.S.C 241a and U.S.C. 288). All analyses conducted on the date of birth, gender, race and/or ethnic origin data will report aggregate statistical findings only and will not identify individuals. If you decline to provide this information, it will in no way affect consideration of your application. Your cooperation will be appreciated.

DATE OF BIRTH (MM/DD/YY)	SEX/GENDER
SOCIAL SECURITY NUMBER (last 4 digits only) XXX-XX-	<input type="checkbox"/> Female <input type="checkbox"/> Male

ETHNICITY

1. Do you consider yourself to be Hispanic or Latino? (See definition below.) Select one.

Hispanic or Latino. A person of Mexican, Puerto Rican, Cuban, South or Central American, or other Spanish culture or origin, regardless of race. The term, "Spanish origin," can be used in addition to "Hispanic or Latino."

Hispanic or Latino

Not Hispanic or Latino

RACE

2. What race do you consider yourself to be? Select one or more of the following.

American Indian or Alaska Native. A person having origins in any of the original peoples of North, Central, **or** South America, and who maintains tribal affiliation or community attachment.

Asian. A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian **subcontinent**, including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. (Note: Individuals from the Philippine Islands have been recorded as Pacific Islanders in previous data collection strategies.)

Black or African American. A person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black" or African American."

Native Hawaiian or Other Pacific Islander. A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or **other** Pacific Islands.

White. A **person** having origins in any of the original peoples of Europe, the Middle East, or North Africa.

Check here if you do not wish to provide some or all of the above information.

Principal Investigator/Program Director (Last, First, Middle):

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: _____

Total Planned Enrollment: _____

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	Sex/Gender		
	Females	Males	Total
Hispanic or Latino			
Not Hispanic or Latino			
Ethnic Category: Total of All Subjects *			
Racial Categories			
American Indian/Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American			
White			
Racial Categories: Total of All Subjects *			

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: _____

Total Enrollment: _____ Protocol Number: _____

Grant Number: _____

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino				**
Not Hispanic or Latino				
Unknown (individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*				*
Racial Categories				
American Indian/Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of All Subjects*				*
PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)				
Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of Hispanics or Latinos**				**

* These totals must agree.

** These totals must agree.

BUDGET of RESEARCH INSTITUTION (STTR ONLY)					FROM	THROUGH	
NAME AND ADDRESS OF RESEARCH INSTITUTION							
PERSONNEL		TYPE APPT. <i>(months)</i>	% EFFORT ON PROJ.	INST. BASE SALARY	DOLLAR AMOUNT REQUESTED <i>(omit cents)</i>		
NAME	ROLE ON PROJECT				SALARY REQUESTED	FRINGE BENEFITS	TOTAL
	Principal Investigator						
SUBTOTALS →						\$	
CONSULTANT COSTS							
EQUIPMENT <i>(Itemize)</i>							
SUPPLIES <i>(Itemize by category)</i>							
TRAVEL							
PATIENT CARE COSTS		INPATIENT					
		OUTPATIENT					
ALTERATIONS AND RENOVATIONS <i>(Itemize by category)</i>							
OTHER EXPENSES <i>(Itemize by category)</i>							
TOTAL DIRECT COSTS (also enter as Consortium/Contractual Costs on Budget Page of Small Business Concern)						\$	
FACILITIES and ADMINISTRATIVE COSTS (show calculation) (also enter as Consortium/Contractual Costs on Budget of Small Business Concern)						\$	
<p>CERTIFICATION OF RESEARCH INSTITUTION PARTICIPATION. Through the signature below of the duly authorized representative of the research institution on this "Certification of Research Institution" page, and by way of the signature of the official signing for applicant organization (small business concern) on the Face Page of the application, the small business concern and the research institution certify <i>jointly</i> that: (1) the proposed STTR project will be conducted jointly by the small business concern and the research institution in which not less than 40 percent of the work will be performed by the small business concern and not less than 30 percent of the work will be performed by the research institution ("cooperative research and development"); (2) the proposed STTR project is a cooperative research or research and development effort to be conducted jointly by the small business concern and the research institution in which not less than 40 percent of the work will be performed by the small business concern and not less than 30 percent of the work will be performed by the research institution ("performance of research and analytical work"); and (3) regardless of the proportion of the proposed project to be performed by each party, the small business concern will be the primary party that will exercise management direction and control of the performance of the project. If the research institution is a contractor-operated federally funded research and development center, the duly authorized representative of the contractor-operated federally funded research and development center certifies, <i>additionally</i>, that it: (4) is free from organizational conflicts of interests relative to the STTR program; (5) did not use privileged information gained through work performed for an STTR agency or private access to STTR agency personnel in the development of this STTR grant application; and (6) used outside peer review, as appropriate, to evaluate the proposed project and its performance therein.</p>							
Signature of Duly Authorized Representative		Printed Name		Title	Date of Signature		

Mailing address for application

Use this label or a facsimile

All applications and other deliveries to the Center for Scientific Review must come either via courier delivery or via the United States Postal Service (USPS.) Applications delivered by individuals to the Center for Scientific Review will no longer be accepted.

Applications sent via the USPS EXPRESS or REGULAR MAIL should be sent to the following address:

**CENTER FOR SCIENTIFIC REVIEW
NATIONAL INSTITUTES OF HEALTH
6701 ROCKLEDGE DRIVE
ROOM 1040 – MSC 7710
BETHESDA, MD 20892-7710**

NOTE: All applications sent via a courier delivery service (non-USPS) should use this address, but CHANGE THE ZIP CODE TO 20817

The telephone number is 301-435-0715. C.O.D. applications will not be accepted.

For application in response to RFA

Use this label or a facsimile

IF THIS APPLICATION IS IN RESPONSE TO AN RFA, be sure to put the RFA number in line 2 of the application face page. In addition, after duplicating copies of the application, cut along the dotted line below and staple the RFA label to the bottom of the face page of the original and place the original on top of your entire package. Failure to use this RFA label could result in delayed processing of your application such that it may not reach the review committee on time for review. ***Do not use*** the label unless the application is in response to a specific RFA. Also, applicants responding to a specific RFA should be sure to follow all special mailing instructions published in the RFA.

RFA No. _____

RFA

Mailing address for application

Use this label or a facsimile

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Applications sent via the USPS EXPRESS or REGULAR MAIL should be sent to the following address:

<p>CENTER FOR SCIENTIFIC REVIEW NATIONAL INSTITUTES OF HEALTH 6701 ROCKLEDGE DRIVE ROOM 1040 – MSC 7710 BETHESDA, MD 20892-7710</p>
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NOTE: All applications sent via a courier delivery service (non-USPS) should use this address, but CHANGE THE ZIP CODE TO 20817

The telephone number is 301-435-0715. C.O.D. applications will not be accepted.

For application in response to SBIR/STTR

Use this label or a facsimile

IF THIS APPLICATION IS IN RESPONSE TO AN SBIR/STTR Solicitation, be sure to put the SBIR/STTR Solicitation number in line 2 of the application face page. In addition, after duplicating copies of the application, cut along the dotted line below and staple the appropriate SBIR or STTR label to the bottom of the face page of the original and place the original on top of your entire package. If this SBIR or STTR application is in response to an RFA, be sure to also include the RFA No. in the space provided below.

SBIR

RFA No. _____ (if applicable)

STTR

RFA No. _____ (if applicable)